UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

FERRING B.V., Plaintiff, vs. WATSON LABORATORIES, INC. - (FL) et al., Defendants.	3:11-cv-00481-RCJ-VPC **ORDER**
FERRING B.V., Plaintiff, vs. APOTEX, INC. et al., Defendants.	3:11-cv-00485-RCJ-VPC **ORDER**
FERRING B.V., Plaintiff, vs. WATSON PHARMACEUTICALS, INC. et al., Defendants.	3:11-cv-00853-RCJ-VPC **ORDER**
FERRING B.V., Plaintiff, vs. APOTEX, INC. et al., Defendants.	3:11-cv-00854-RCJ-VPC **ORDER**

These four consolidated cases arise out of Defendants' application with the Food and Drug Administration ("FDA") to manufacture and sell generic versions of a patented drug. Pending before the Court are the parties' claim construction briefs.

I. FACTS AND PROCEDURAL HISTORY

These cases arise out of the alleged infringement of Plaintiff Ferring B.V.'s ("Ferring") U.S. Patent No. 7,947,739 for tranexamic acid tablets sold under the trademark Lysteda® (the "'739 Patent" or "Tablet Patent"), (*see* Compl. ¶¶ 13–17, July 7, 2011, ECF No. 1; Compl. ¶¶ 9–13, July 8, 2011, ECF No. 1 in Case No. 3:11-cv-00485), and the alleged infringement of Ferring's U.S. Patent No. 8,022,106 for tranexamic acid formulations and methods of treating menorrhagia therewith (the "'106 Patent" or "Formulas and Treatment Patent"), (*see* Compl. ¶¶ 13–17, Nov. 25, 2011, ECF No. 1 in Case No. 3:11-cv-00853; Compl. ¶¶ 9–13, Nov. 25, 2011, ECF No. 1 in Case No. 3:11-cv-00854).[1] In the '481 and '485 Cases, respectively, Ferring sued several Watson Labs entities (collectively, "Watson Defendants") and several Apotex entities (collectively, "Apotex Defendants") in this Court for infringing the '739 Patent. In the '853 and '854 Cases, respectively, Ferring sued several Watson Defendants and several Apotex Defendants in this Court for infringing the '106 Patent.

The Court consolidated the four cases, with the '481 Case as the lead case. It also granted motions to dismiss the counterclaims for invalidity and to strike affirmative defenses for invalidity in the '481 and '854 Cases, with leave to amend. The Court ruled that affirmative defenses must specify a distinct legal theory of invalidity under Rule 8(c) but need not be pled according to the *Iqbal* plausibility standard, as the counterclaims must be under Rule 8(a). Watson Defendants and Apotex Defendants amended their answers and counterclaims, accordingly. (*See* ECF Nos. 93, 94). Apotex Defendants later further amended its answer and

[1]Unless otherwise noted, the docket numbers in this document refer to Case No. 3:11-cv-00481.

counterclaim. The Court has denied motions to dismiss the amended counterclaims for invalidity.

In preparation for the *Markman* hearing, and in accordance with the local rules, the parties submitted a Joint Claim Construction and Prehearing Statement ("JCCPHS"), in which they claim to have exchanged proposed terms for claim construction, met and conferred regarding those proposed terms, and exchanged preliminary constructions and supporting evidence. The parties agreed on none of the terms that they believe the Court must construe. The Court held a *Markman* hearing.

II. LEGAL STANDARDS

"[T]he interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970–71 (Fed. Cir. 1995) (en banc) (affirming a district court's grant of a motion for judgment as a matter of law after a jury found infringement based upon its incorrectly broad construction of a patent claim).[2] Despite pre-*Markman* inconsistencies in the Federal Circuit's case law on the question of whether a jury properly had any role in construing patent claims, the Supreme Court had consistently ruled that claim construction was a purely legal issue. *Id.* at 977–78 (collecting cases). This is because a patent claim, like a contract, is a written instrument uniquely suited to interpretation by a court as a matter of law. *Id.* at 978.

A "*Markman* hearing" is an extended evidentiary hearing culminating in a claim construction order, the language of which will inform the jury as to its determination of infringement at the trial itself. At the hearing, a district court hears evidence concerning the claims, the specifications, the prosecution history, and any extrinsic evidence helpful to the court

[2]"Claim construction" and "claim interpretation" are synonymous in the patent law context. *Id.* 52 F.3d at 976 n.6.

in understanding the patent:

> To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history. Expert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used. . . .
>
> Claims must be read in view of the specification, of which they are a part. The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. As we have often stated, a patentee is free to be his own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.
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> To construe claim language, the court should also consider the patent's prosecution history, if it is in evidence. This undisputed public record of proceedings in the Patent and Trademark Office is of primary significance in understanding the claims. The court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims. . . . Although the prosecution history can and should be used to understand the language used in the claims, it too cannot enlarge, diminish, or vary the limitations in the claims.
>
> Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises. This evidence may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history. Extrinsic evidence may demonstrate the state of the prior art at the time of the invention. It is useful to show what was then old, to distinguish what was new, and to aid the court in the construction of the patent.
>
> The court may, in its discretion, receive extrinsic evidence in order to aid the court in coming to a correct conclusion as to the true meaning of the language employed in the patent.
>
> Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims. When, after considering the extrinsic evidence, the court finally arrives at an understanding of the language as used in the patent and prosecution history, the court must then pronounce as a matter of law the meaning of that language. This ordinarily can be accomplished by the court in framing its charge to the jury, but may also be done in the context of dispositive motions such as those seeking judgment as a matter of law.
>
> Through this process of construing claims by, among other things, using certain extrinsic evidence that the court finds helpful and rejecting other evidence as unhelpful, and resolving disputes en route to pronouncing the meaning of claim language as a matter of law based on the patent documents themselves, the court is

> not crediting certain evidence over other evidence or making factual evidentiary findings. Rather, the court is looking to the extrinsic evidence to assist in its construction of the written document, a task it is required to perform. The district court's claim construction, enlightened by such extrinsic evidence as may be helpful, is still based upon the patent and prosecution history.

Id. at 979–81 (internal quotation marks, footnotes, and citations omitted). The Supreme Court unanimously affirmed. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) ("We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.").

Certain kinds of evidence are given more weight than other kinds, in the following order: terms as used within the claims themselves, the descriptive part of the specifications, the patent prosecution history, and finally, extrinsic evidence, which is inherently less reliable than intrinsic evidence and is therefore only viable for use in interpreting claims directly where the available intrinsic evidence is insufficient. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314–19 (Fed. Cir. 2005) (en banc). Claims are given their ordinary meaning as they would be understood by a person of ordinary skill in the relevant art at the time of the effective filing date of the patent. *Id.* at 1312–13.

III. ANALYSIS

In Exhibits A, B, and C to the JCCPHS, respectively, Plaintiff, Watson Defendants, and Apotex Defendants have adduced their proposed claim constructions and specified supporting evidence. Plaintiff has used a memorandum format, and Defendants have used table formats. Although styled as "claim constructions," the parties have not adduced proposed claim constructions as to entire claims but have proposed definitions for certain terms included within the claims.

A. The '739 Patent

1. The Claims

The purpose of the '739 Patent is to create "modified release oral tranexamic acid

formulations that preferably minimize or eliminate undesirable side effects and methods of treatment with these formulations." (*See* '739 Patent col. 1, ll. 16–19, ECF No. 204 Ex. 1). Transexamic acid is used to control bleeding during dental surgery on hemophiliacs and during menstruation. (*See id.* col. 1, ll. 33–36). Women using the drug typically ingest 3–6 grams a day, but this dosage can cause negative gastrointestinal side effects—effects the '739 Patent aims to minimize or eliminate via a modified release mechanism that prevents excess tranexamic acid from collecting in the stomach and intestinal tract. (*See id.* at col. 1, ll. 36–51; *id.* col. 6, ll. 3–18). The '739 Patent makes nineteen claims, three of which are independent (Claims 1, 11, and 16), ten of which depend on Claim 1 (Claims 2–6, 8–10, 12–13), two of which depend in turn on Claim 5 (Claims 7 and 14), one of which depends further in turn on Claim 14 (Claim 15), one of which depends on Claim 11 (Claim 18), one of which depends in turn on Claim 18 (Claim 19), and one of which depends on Claim 16 (Claim 17). Plaintiff has not specified which of the claims Defendants are alleged to have infringed but only that they have infringed "at least one of the claims."

Claim 1 reads:

> A tranexamic acid tablet formulation, comprising:
>
> tranexamic acid or a pharmaceutically acceptable salt thereof; and
>
> a modified release material, wherein the modified release material comprises a polymer selected from the group consisting of hydroxyalkylcelluloses, alkylcelluloses, cellulose ethers, partial esters thereof, and mixtures thereof;
>
> wherein the modified release material is present in the formulation in an amount from about 10% to about 35% by weight of the formulation;
>
> wherein the formulation provides an in-vitro dissolution release rate of the tranexamic acid or pharmaceutically acceptable salt thereof, when measured by the USP 27 Apparatus Type II Paddle Method @ 50 RPM in 900 mL water at 37±0.5˚C, of less than about 70% by weight tranexamic acid or pharmaceutically acceptable salt thereof released at about 45 minutes, and about 100% by weight tranexamic acid or pharmaceutically acceptable salt thereof released by about 120 minutes; and

> wherein each tablet of the formulation provides a dose of about 650 mg of tranexamic acid.

(*See id.* col. 69, ll. 45–67). First, the claim includes any "pharmaceutically acceptable salt" of tranexamic acid within its definition of "tranexamic acid" in the first limitation, in order to allow for tablets comprised of various salts of tranexamic acid. The Claim therefore covers tablets not only with tranexamic acid itself, but tablets with any salt of tranexamic acid that is suitable for human ingestion. Second, the claim includes the significant limitation that the "modified release material" in the tablet must be "a polymer selected from the group consisting of hydroxyalkylcelluloses, alkylcelluloses, cellulose ethers, partial esters thereof, and mixtures thereof." Tablets with modified release materials comprised of other substances are therefore not claimed. Third, only tablets where the modified release material is present between "about" 10% and 35% are covered. Because the term "about" is not readily capable of mathematical translation, unless the term is addressed in the specifications, which it is not, expert testimony may be relevant to understand the scope of the range claimed. Fourth, the claim is limited to tablets where less than "about" 70% of the weight of the transexamic acid in the tablet is released after "about" 120 minutes under the specified laboratory conditions. Fifth, the claim is limited to tablets that deliver a dose of "about" 650 mg of tranexamic acid. Also, the phrase "or a pharmaceutically acceptable salt thereof" does not appear in the fifth limitation, likely because once administered, the acid (the positive ion) dissociates from the negative ion (a chloride or the like), whereas the solid tablet as described in the first limitation may exist as a "salt," i.e., molecules or matrices of positive acid ions and negative ions such as halogens, as opposed to hydroxide.

Claim 2 adds a sixth limitation to Claim 1 wherein about 15-29% by weight of the acid is released under the specified laboratory conditions by about 15 minutes, about 56-69% is released by about 45 minutes, and about 89-100% by about 90 minutes.

Claim 3 adds a sixth limitation to Claim 1 wherein the tablet consists of a "matrix tablet," i.e., "a pregranulated drug mixed together with the modified release material."

Claim 4 adds a sixth limitation to Claim 1 wherein the modified release material comprises a hydroxyalkylcellulose or a celluslose ether.

Claim 5 adds a sixth limitation to Claim 1 wherein the modified release material comprises hydroxyproplymethylcellulose.

Claim 6 adds a sixth limitation to Claim 1 wherein the modified release material is present in about 15% by weight of the formulation.

Claim 7 adds a seventh limitation to Claim 5 wherein the modified release material is present in about 15% by weight of the formulation.

Claim 8 adds a sixth limitation to Claim 1 wherein a single administration of a dose of 1300 mg (two tablets) provides a maximum plasma concentration of tranexamic acid from about 9 to 14.5 mcg/mL.

Claim 9 adds a sixth limitation to Claim 1 wherein a single administration of a dose of 1300 mg (two tablets) provides a maximum plasma concentration of tranexamic acid from about 12.5 to 25 mcg/mL.

Claim 10 adds a sixth limitation to Claim 1 wherein the time to the maximum plasma concentration of tranexamic acid is about two to three-and-a-half hours after a single dose.

Claim 11 is a variation of Claim 1 also containing five limitations. The second limitation is modified to specify an "effective amount of" a modified release material, and the fourth limitation is modified to specify that the formulation releases about 10% to 25% by weight of the tranexamic acid or salt thereof every 15 minutes, and all of the acid within 120 minutes.

Claim 12 adds a sixth limitation to Claim 1 wherein the administration of a dose of 1300 mg (two tablets) three times daily provides a mean maximum plasma concentration of tranexamic acid from about 10 to 20 mcg/mL after multi-dose administration.

Claim 13 adds a sixth limitation to Claim 1 wherein a single administration of a dose of 1300 mg (two tablets) provides a mean maximum plasma concentration of tranexamic acid from about 9 to 17.5 mcg/mL.

Claim 14 adds a seventh limitation to Claim 5 wherein the hydroxypropylmethylcellulose is present in about 10% to 35% by weight of the formulation.

Claim 15 adds an eighth limitation to Claim 14 wherein the hydroxypropylmethylcellulose is present in about 15% by weight of the formulation.

Claim 16 is a variation of Claim 1 containing four limitations. The second and third limitations of Claim 1 are modified into a single second limitation of Claim 16 requiring that hydroxypropylmethylcellulose is present in about 10% to 35% by weight of the formulation.

Claim 17 adds a fifth limitation to Claim 16 wherein the hydroxypropylmethylcellulose is present in about 15% by weight of the formulation.

Claim 18 adds a sixth limitation to Claim 11 wherein hydroxypropylmethylcellulose is present in about 10% to 35% by weight of the formulation.[3]

Claim 19 adds a seventh limitation to Claim 18 wherein hydroxypropylmethylcellulose is present in about 15% by weight of the formulation.

2. The Parties' Proposed Claim Constructions

a. "tablet formulation"

Plaintiff proposes that this term means "active pharmaceutical ingredient and excipients compressed together." In other words, according to Plaintiff, "tablet formulation" means the entire pill, including inactive substances that are a part of the tablet a patient swallows. Defendants propose that this term means "a finished oral dosage form in tablet form." It is not

[3]Although written as dependent on Claim 11, it appears that Claim 18 was originally intended to be independent, because it includes four of its own limitations, three of which are redundant with limitations already present under Claim 11. The result is the same.

clear what the difference between these two definitions is, but Plaintiff's definition is clearer. It is also a more straightforward and commonsense definition. The term "dosage" would appear to refer to the amount of active ingredient to be given to a patient (in some form), and the term "tablet dosage" would appear to refer to this amount of active ingredient compressed into a tablet, together with any amount of inactive substance. But the term "tablet formulation" would appear to refer to the formula of a tablet as a whole, i.e., the percentages of active and inactive ingredients in the entire tablet. As such, Plaintiff's construction appears to be correct, and Defendants' construction does not appear to contradict it, though it is unnecessarily confusing and unclear. What is "a finished oral dosage form in tablet form?" The "form" of the object is a tablet. A dosage is not a "form" but a quantity, i.e., a mass or a volume of active ingredient. Therefore, a better construction in Defendants' style would read, "a finished oral dosage in tablet form." But what is a "finished" dosage as opposed to an "unfinished" dosage? Do Defendants simply mean to imply that "tablet formulation" applies only to tablets that have been completely manufactured and not those that have only been partially manufactured? How could such a construction aid Defendants? Do they intend to argue that they sell or intend to sell only "unfinished" tablets, as opposed to "finished" tablets? Aren't the tablets they allegedly sell or intend to sell "finished" by definition once they are taken off the assembly line? An even better construction in Defendants' style would therefore read, "an oral dosage in tablet form." And how is this different from "active pharmaceutical ingredient and excipients compressed together?" Plaintiff's construction better explains what "tablet formulation" means. The common meanings of these words as used in the claims are sufficient to construe the term, and the Court need not examine the specifications, patent prosecution history, or extrinsic evidence.

b. "modified release material"

Plaintiff proposes that this term means "a material that modifies the release of the active pharmaceutical ingredient." In other words, an excipient material in a tablet that alters the rate

of release of the active pharmaceutical ingredient. Defendants propose that this term means "a polymer selected from the group of hydroxyalkylcelluloses, cellulose ethers, or partial esters thereof that act to slow the release of tranexamic acid in the water medium used in the 27 USP Apparatus Type II test." In other words, Defendants' wish to limit the term to very particular kinds of materials (hydroxyalkylcelluloses, cellulose ethers, or partial esters thereof) and also to note that the rate refers specifically to the rate achieved under particular test conditions.

The Court adopts Plaintiff's construction. Each of the independent claims that include the present term contain limitations that make Defendants' proposed construction either partially redundant or plainly incorrect. For example, the independent claims already indicate as a limitation that the modified release material must be made of the substances Defendants specify in their proposed construction of the term "modified release material," or some other more specific substance. And in some of the claims, the composition of the modified release material is further limited in such a way that the independent claims would be rendered internally inconsistent if the term "modified release material" were to be construed always to imply the limitations on composition separately identified in the limitations of the independent claims. Defendants' language about the function of the modified release material is also redundant in light of the separate limitations in the independent claims indicating the function.

c. "release rate"

Plaintiff proposes that this term means "the percentage of active pharmaceutical ingredient released in a given time." Defendants propose that this term means "the rate at which tranexamic acid or a pharmaceutically acceptable salt thereof is released from the tablet formulation in the water medium used in the 27 USP Apparatus Type II test."

Defendants are correct that the summary of the invention in the specifications indicates that release rate is measured specifically. (*See, e.g.*, '739 Patent col. 6, ll. 56–60). In fact, the release rate is defined in the claims and throughout the specifications even more specifically as

"when measured by the USP 27 Apparatus Type II Paddle Method @ 50 RPM in 900 mL water at 37±0.5°C." (*See id. passim*). The Court adopts Plaintiff's construction. The construction Defendants propose unnecessarily imports additional information from the specifications and is redundant with limitations in the claims.

d. "about 10% to about 35% by weight of the formulation"

Plaintiff proposes that this term includes quantities within 10% of the specified value. It is not clear whether Plaintiff means 0% to 45%, which is an unlikely interpretation of "about 10% to about 35%," or whether it means 9% to 38.5%, which is obtained by subtracting or adding 10% of the limits of the range, respectively. Defendants propose that this term includes a range of 9.5% to 36.75% by weight, which corresponds to the subtraction or addition of 5% to the limits of the range, respectively.

The claims and the specifications use the term "about" often but never attempt to define it numerically. In 2007, the Federal Circuit was faced with the task of construing the term "about 1:5" in the context of the ratio of tramadol to acetaminophen in a pain reliever pill. *See Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321 (Fed. Cir. 2007). The parties agreed that the term meant "approximately," but the stipulation to a synonym still left the court with no mathematically useful interpretation. *See id.* at 1326. The defendant argued that the scope of the claim was no more than 5–10% of the specified ratio (1:5) due to the confidence levels reported in the specifications of the patent, but the plaintiff argued that the scope of the claim was a ratio from at least 1:3.6 to 1:7.1. *Id.* at 1324. The district court adopted the plaintiff's proposed construction based upon the claims and specifications, as well as the extrinsic testimony of two medical doctors that the outer ratios argued by the plaintiff would be statistically indistinguishable from 1:5 to a person or ordinary skill in the art. *Id.* The Court of Appeals noted that words such as "about" are to be construed consistently with the technological facts of a particular case. *See id.* at 1326 (quoting *Pall Corp. v. Micron Separations, Inc.*, 66

F.3d 1211, 1217 (Fed. Cir. 1995)). The court concluded that in the case before it, the plaintiff's patent used ratios both alone and in ranges, and the court therefore concluded that "one of ordinary skill in the art would understand the inventors intended a range when they claimed one and something more precise when they did not." *Id.* at 1327. Two concise paragraphs of the specifications of the patent at issue discussed common ranges of tramadol–acetaminophen ratios in pills, optimal ranges of tramadol–acetaminophen ratios, and then concluded by noting that the patent included the discrete ratios of 1:1 and 1:5. *Id.* The Court of Appeals reasoned:

> These paragraphs suggest that the qualifier "about" is narrow because to find otherwise would allow the scope of the more specifically identified ratio, 1:5, to encompass a range of ratios that could potentially render meaningless another claim's limitation, namely the 1:1 limitation.
>
> Furthermore, the data points from the experiments described in the specification support a conclusion that the more specifically identified ratio of 1:5 was meant to encompass compositions very close to that ratio. The experiments disclosed in the specification show data points for ratios of tramadol to acetaminophen in the lower ratio quadrant of 1:1, 1:3, 1:5, 1:5.7, and 1:15. Yet, the patentees chose to specifically claim ratios of 1:1 and 1:5. If the data suggested to the inventors that a range of ratios in this lower ratio quadrant was desirable, they could easily have claimed a ratio range of "about 1:1 to about 1:5," or even a ratio range of "about 1:3 to about 1:5," but they did not. Instead, they chose a specific data point for claim 6 of precisely 1:5. Moreover, the identification of the 1:5 ratio in both claim 6 and the specification is especially important when the only other specifically identified ratio is close to it, 1:1, and the other claims point to a broad range of ratios. This dichotomy between the specific ratio of 1:5 and the broader ratio ranges of the other claims points to a narrow scope for the "about 1:5" limitation.

Id. at 1327–28 (citations omitted).

Here, the parties dispute the meaning of "about" in the context of a claim limitation that the modified release material is present in "about" 10% to 35% by weight of the tablet. In support of its position, Plaintiff points to the claims themselves and to specifications within the patent that recount the preparation of 84.5 kg batches of 650 mg tablets, but which do not indicate any variation in the concentration of modified release material either by batch or by tablet. (*See* '739 Patent col. 28, l. 23 to col 29., l. 3). The ingredients in the "Example 1" batch

that appear to be polymers corresponding to the list in Claim 1 are Microcrystalline Cellulose NF (Avicel PH 101) and Hypromellose, USP (Methocol K3 Premium LV), which are present in each 650 mg tablet in amounts of 44.25 mg and 147.00 mg, respectively, for a total modified release material of 29.42% by weight, which is well within the 10% to 35% range of the third limitation of Claim 1. (*See id.* tbl.1). In Example 2, the modified release materials are present at 21.73%. (*See id.* tbl. 2). In Example 3, the modified release materials are present at 29.42%. (*See id.* tbl. 3). In Example 3a, the modified release materials are present at 21.73%. (*See id.* tbl. 3A). The examples do not include error ranges. The percentage of each ingredient in each batch of tablets is very precisely given, much more precisely than the ratios given in *Ortho-McNeil*, and no ranges are suggested, either by design or as a result of error calculations. Defendants recount much of this and then suggest a 5% variation down from 10% and up from 35%, i.e., a range of 9.5% to 36.75%, based upon the declarations of their expert and an FDA manual.

In summary, the 10% to 35% limitation appears to claim more than what was reported as having been tested in the specifications, and this limitation already provides a large "about"-type buffer for variation well beyond Defendants' claimed industry-standard 5% variation and Plaintiff's claimed industry-standard 10% variation. Under these circumstances, where the specifications indicate a level of precision far beyond that given in the claim, and where the relevant limitation in the claim is already significantly broader than the range of precise percentages given in the tests reported in the specifications, the Court might read the term "about" in the claims to be superfluous, except to the extent it may refer to error extrinsic to the intended design of the invention, such as manufacturing error. The Court will not ignore a term in a claim, however. The Court rules that "about" means "approximately" and will instruct the jury no more specifically. The jury can determine what the word "approximately" means.

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e. "about" as used in connection with an amount of active pharmaceutical ingredient released

Plaintiff proposes that this term includes quantities within 10% of the specified value. Defendants propose that the term means "plus or minus 5% by weight of the stated value." The specifications include Table 10A, which lists percentages of dissolution at 15, 45, and 90 minutes for eleven batches of the formula represented in Example 1. (*See* '739 Patent tbl.10A). As Defendants note, the greatest standard deviation within any batch was the standard deviation for batch 3 at 45 minutes, which was 4.366%. (*See id.*). Most of the standard deviations are between 2–3%. (*See id.*). Claim 1 claims dissolution of less than "about" 70% by weight by "about" 45 minutes and "about" 100% by "about" 120 minutes. Table 10A indicates that in the eleven tested batches, between 56% and 69% dissolution by 45 minutes.

The Court might adopt something more like Plaintiff's construction of "about" in the present context, because the specifications indicate that "about" in this context means anywhere from 56% to 69%. (*See id.*). In fact, based upon the specifications, Plaintiff could plausibly argue that the term "about" in the present context means up to a 20% variation in the specified value, because 70% reduced by 20% is 56%, which is one of the results within the range given in the relevant tests in the specifications. However, "about" in the present context could also be interpreted to include only downward variations, not upward variations, because the claim uses the upper level (in fact, one percentage point above the upper level) of the relevant tests in the specifications as a starting point, as opposed to the midpoint. In light of the specifications, "about 70%" in Claim 1 could be read to mean something like "51% to 76%," which would represent the 56% to 69% results in the specifications, with the USP-standard 10% variation added for error. The term "about 100%" could likewise be read to mean something like "at least 89%." There is no indication in Table 10A of the results at 120 minutes, which is relevant to Claim 1, but the results at 90 minutes are between 89% and 100% dissolution. (*See id.*).

Although the specifications include no 120-minute results, because of the scientific principle of entropy, there is no danger that the amount dissolved at 120 minutes is less than the amount dissolved at 90 minutes. If anything, the patentee has claimed less than he might have based upon the specifications.

On the other hand, the 56% to 69% numbers and the 89% to 100% numbers are accounted for in the additional limitation given to Claim 1 by Claim 2, which claim itself uses the term "about" to further modify those numbers, indicating that the term "about" in this context has a broader meaning. This brings the Court back to a choice between a 5% and 10% variation. The Court will rule as it has, *supra*, that "about" means "approximately," and allow the parties to argue the issue to the jury on this basis.

f. "about" as used in connection with time values

Plaintiff proposes that this term includes quantities within 10% of the specified value. Defendants propose that the term means "plus or minus 2% of the stated point in time." Plaintiff points to the claims themselves and to Example 1 in the specifications, none of which is helpful in interpreting the term.

The Court could find that the word "about" as it relates to time values leaves very little room for variation. Although concentrations of chemicals at given times may vary from test to test because of the difficulties in conducting complex chemical experiments, there is no reason there should necessarily be significant variations in time values. Presumably, an experimenter is capable of timing an experiment to at least the nearest second. There may be some experimental variation in time measurements if the apparatus used to take the reading requires the experimenter to do some "fidgeting" to remove a sample, insert a test probe, or the like. But the specifications do not indicate what this time variation might be in the present context. Defendants point out that the USP standards require measurements to be taken within 2% of the stated time points. It is unclear where Plaintiff obtained its 10% figure. The Court will rule as it

has, *supra*, that "about" means "approximately," and allow the parties to argue the issue to the jury on this basis.

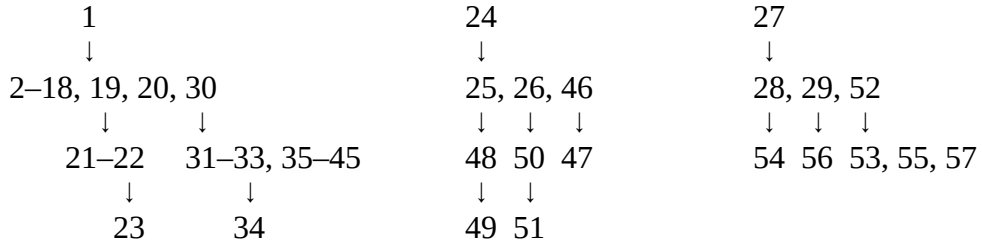
g. "about" as used in connection with the maximum concentration of tranexamic acid in blood plasma ("C_{max}") and the time to reach C_{max} ("T_{max}")

Plaintiff proposes that this term includes quantities within 20% of the specified value. Defendants propose, contrary to the presumption of validity, that "no construction [is] possible" for this term. Plaintiff points to the specifications and industry standards indicating that if the 90% confidence interval of the mean ratio of C_{max} is within 80% to 125%, the formulations are bioequivalent because of the inherent degree of variability between persons. Plaintiff argues that this means the claims for C_{max} and T_{max} include a 20% variation. Defendants point to the declaration of a doctor expert who claims that "about" in this context is insolulably vague and not understandable to persons of skill in the art. The term "about" are not any vaguer as used here than in the other instances. The Court will rule as it has, *supra*, that "about" means "approximately," and allow the parties to argue the issue to the jury on this basis.

B. The '106 Patent

1. The Claims

The purpose of the '106 Patent is the same as that of the '739 Patent. The claims in the '106 Patent consist of variations of the claims in the '739 Patent, but the claims are more numerous and further refined. The '106 Patent makes fifty-seven claims, the dependence of which is illustrated in the following diagram:



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2. The Parties' Proposed Claim Constructions

a. "dosage form"

Plaintiff proposes that this term means "active pharmaceutical ingredient and excipients together." In other words, the physical state and chemical composition of the entire mass intended to be ingested by the patient. Defendants do not address this term. The Court adopts Plaintiff's construction.

b. "oral dosage form"

Plaintiff proposes that this term means "active pharmaceutical ingredient and excipients together, suitable for ingestion by mouth." In other words, the physical state and chemical composition of the entire mass intended to be ingested by the patient by mouth, which is a logical extension of Plaintiff's proposed interpretation of "dosage form." Defendants propose that the term means "a finished oral dosage form in which a drug is produced and dispensed." The Court adopts Plaintiff's construction.

c. "suitable for administration"

Plaintiff proposes that this term means "capable of being given, taken, dosed, or ingested." Defendants propose that this term means "in a form approved by the FDA to be administered to a human." Plaintiff points to portions of the specifications concerning oral dosages, ingestion by mouth in tablets of 0.5 to 1.0 grams, and dissolution in the stomach fluids. Defendants point to no evidence indicating that this term implies approval by the FDA. The Court adopts Plaintiff's construction.

d. "formulation"

Plaintiff proposes that this term means "active pharmaceutical ingredient and excipients together." This is the same as Plaintiff's proposed interpretation of "tablet formulation" under the '739 Patent, minus the word "compressed," and the same as its proposed interpretation for "dosage form." Defendants propose that the term means the same as "an oral dosage form." The

Court adopts Plaintiff's construction.

e. Remaining Terms

The six remaining disputed terms under the '106 Patent are the same as six of the seven disputed terms under the '739 Patent *supra*, excluding "tablet formulation," and the parties make the same arguments as to their proper construction. The Court rules as it rules under the '739 Patent.

CONCLUSION

IT IS HEREBY ORDERED that the disputed terms are construed as follws:

Term	**Construction**
tablet formulation	active pharmaceutical ingredient and excipients compressed together
modified release material	a material that modifies the release of the active pharmaceutical ingredient
release rate	the percentage of active pharmaceutical ingredient released in a given time
about (in all challenged contexts)	approximately
oral dosage form	active pharmaceutical ingredient and excipients together, suitable for ingestion by mouth
dosage form	active pharmaceutical ingredient and excipients together
suitable for administration	capable of being given, taken, dosed, or ingested
formulation	active pharmaceutical ingredient and excipients together

IT IS SO ORDERED.

Dated this 6th day of February, 2013.

ROBERT C. JONES
United States District Judge